

# **EXHIBIT**

# **O**

MYLAN PHARMACEUTICALS, INC., et al., Plaintiffs, v. KREMERS URBAN DEVELOPMENT, et al.,  
Defendants.

C.A. No. 02-1628 GMS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2003 U.S. Dist. LEXIS 20665

November 14, 2003, Decided

**SUBSEQUENT HISTORY:** Patent interpreted by, Motion denied by **Mylan Pharms., Inc. v. Kremers Urban Dev. Co., 2004 U.S. Dist. LEXIS 391 (D. Del., Jan. 13, 2004)**

**PRIOR HISTORY:** **Mylan Pharms., Inc. v. Kremers Urban Dev. Co., 2003 U.S. Dist. LEXIS 5728 (D. Del., Apr. 7, 2003)**

**DISPOSITION:** { \*1 } Plaintiff's Motion for Leave to Amend GRANTED.

**COUNSEL:** For Mylan Pharmaceuticals Inc, Esteve Quimica, SA, PLAINTIFFS: John W Shaw, Young, Conaway, Stargatt & Taylor, Wilmington, DE USA.

For Kremers Urban Development Company, Schwarz Pharma Inc, Schwarz Pharma Manufacturing, Inc, Schwarz Pharma-Group USA, DEFENDANTS: Philip A Rovner, Potter Anderson & Corroon, LLP, Wilmington, DE USA.

**JUDGES:** Gregory M. Sleet, UNITED STATES DISTRICT JUDGE.

**OPINION BY:** Gregory M. Sleet

## **OPINION: MEMORANDUM AND ORDER**

### **I. INTRODUCTION**

On November 2, 2002, plaintiff, Mylan Pharmaceuticals Inc. ("Mylan"), filed the above-captioned action alleging infringement of the '875 patent and tortious interference by the defendants, Kremers Urban Development Company, Schwartz Pharma, Inc., Schwartz Pharma Manufacturing, Inc., Schwartz Pharma USA Holdings, Inc. and Kremers Urban, Inc. (collectively "Kremers"). On January 2, 2003, Mylan filed an amended complaint joining the plaintiff, Esteve Quimica, S.A. ("Esteve" or collectively with Mylan, "Mylan"), a corporation organized under the laws of Spain with its principal place of business in Spain and the assignee of the '875 patent. On April 4, 2003, Mylan { \*2 } filed a second amended complaint correcting the name of one of the defendants.

Presently before the court is Mylan's motion for leave to file a third amended complaint adding two new

defendants, Dr. Pawn Seth and Dr. Andre Stamm, and alleging four new counts for transfer of ownership of the '499, '198, and '355 patents, infringement of the '499, '198, and '355 patents, misappropriation of trade secrets technology and know-how, and conversion, respectively. For the following reasons, the court will grant this motion.

### **II. BACKGROUND**

The existing complaint alleges that Kremers' manufacturing and marketing of omeprazole generic drug infringes Mylan's '875 patent and tortiously interferes with Mylan's prospective business opportunity to the sole use of its patented invention and the right to compete fairly for customers. After Mylan joined Esteve in this action, it undertook further investigation of these issues during discovery. In doing so, Mylan uncovered proof that two Esteve consultants, Dr. Seth and Dr. Stamm, misappropriated certain trade secrets, know-how, and other proprietary information regarding the development and manufacture of omeprazole. This proprietary information, { \*3 } Mylan claims, is the exclusive property of Esteve pursuant to the terms of an agreement between Saltrade Ltd. and Laboratorios Esteve, S.A. (hereinafter the "Saltrade Agreement"), n1 an affiliate of plaintiff Esteve. According to Mylan, Dr. Seth and Dr. Stamm used the know-how they misappropriated from Esteve to develop the omeprazole formula that is the subject of the '499, '198, and '355 patents assigned to Schwartz Pharma A.G. upon issuing. Mylan contends that those three patents, therefore, rightfully belong to itself and not to Schwartz Pharma A.G. or any of the other defendants.

--Footnotes--

n1 The pertinent section of the Saltrade Agreement states, "SALTRADE hereby transfers to ESTEVE on exclusive basis on the KNOW-HOW to manufacture the PRODUCT." "Know-how" is defined to mean "a body of technical information, documentation and data which refer to the

process technology, machinery required and analytical technology used in manufacture, testing and analysis of the PRODUCT." "Product" is defined to mean OMEPRAZOLE PELLETS, bioequivalent to \*ANTRA pellets."

-- -End Footnotes-- -

{\*4}

Mylan's allegations are reflected in the proposed amended complaint by four new counts, modification of the existing tortious interference count, and the addition of two defendants, Dr. Seth and Dr. Stamm. Count Two of Mylan's proposed amended complaint alleges that Dr. Seth and Dr. Stamm improperly obtained and assigned to Schwartz Pharma A.G. the '499, '198, and '355 patents for a formulation of omeprazole. Count Three then claims that Kremers marketing of omeprazole infringes the '499, '198, and '355 patents. In Count Five, Mylan asserts that Dr. Seth and Dr. Stamm, in addition to the other defendants, misappropriated confidential technology and know-how that Dr. Seth gained during his association with Esteve and that was the exclusive property of Esteve. Mylan also seeks to amend its tortious interference claim in Count Four to include allegations that Dr. Seth and Dr. Stamm conspired to misappropriate confidential technology and know-how that was the exclusive property of Esteve. In Count Six of the proposed amended complaint, Mylan alleges that the defendants' receipt of profits from the sale of omeprazole constitutes conversion of funds properly belonging to Mylan.

Mylan claims {\*5} it should be permitted to amend the complaint because the facts supporting the additional counts and joinder of parties were ascertained and developed during discovery. Kremers contends that the amendments are prejudicial because Mylan seeks to add four entirely new claims concerning three new patents and two new defendants at a late date in the case which would require reworking of the case management plan and rescheduling of the trial date. Kremers also makes a series of arguments claiming that Mylan's motion for leave to amend is also futile. It argues that Mylan lacks standing to claim patent infringement over the '499, '198, and '355 patents. Kremers also contends that the court lacks subject matter jurisdiction over the claims and personal jurisdiction over Dr. Seth and Dr. Stamm. It further argues that the new claims must be settled through arbitration because they arise out of the Saltrade Agreement which contains an arbitration provision. The tort claims, Kremers asserts, are barred by the three-year statute of limitations because Esteve was aware of the underlying facts as early as 1996.

Kremers makes additional arguments that Mylan improperly relies on Delaware law, the {\*6} Saltrade Agreement does not transfer a future interest in all omeprazole technology, and the conversion and tortious interference counts fail to state claims upon which relief may be granted. The court disagrees with these contentions.

### III. STANDARD OF REVIEW

**Rule 15 of the Federal Rules of Civil Procedure** permits a party to amend the complaint by leave of court or by written consent of the adverse party. Leave to amend a complaint should be "freely given when justice so requires." **Fed. R. Civ. P. 15(a)**. The court has discretion to deny leave to amend when there exists undue delay, bad faith, dilatory motive or undue prejudice to the opposing party, or when the amendment would be futile. *See Foman v. Davis*, 371 U.S. 178, 182, 9 L. Ed. 2d 222, 83 S. Ct. 227 (1962); *Cureton v. NCAA*, 252 F.3d 267, 273 (3d Cir. 2001). Specifically, an amendment would be futile for purposes of **Rule 15(a)** if, accepting all the well pleaded facts as true, the amended complaint fails to state a claim upon which relief may be granted. *See Satellite Fin. Planning Corp. v. First Nat'l Bank of Wilmington*, 646 F. Supp. 118, 120 (D. Del 1986). {\*7} In other words, "the court should apply the same standards as are applied to **Rule 12(b)(6)** motions to dismiss." *Id.*

### IV. DISCUSSION

The court does not find the relevant factors to weigh against granting leave to amend the complaint to add Dr. Seth and Dr. Stamm as defendants and to include the proposed new and modified claims for transfer of ownership, infringement, tortious interference, misappropriation of trade secrets and conversion.

#### **A. Mylan Has Neither Unduly Delayed Nor Exhibited Bad Faith in Seeking to Amend the Complaint, and Kremers Will Not Be Significantly Prejudiced by the Amendments.**

Having discovered the factual basis for the claims only after conducting discovery, Mylan timely seeks to amend its complaint to include the proposed counts. Mylan has not unduly delayed in seeking leave to amend the complaint to add the new counts, nor does its motion for leave appear to arise out of any bad faith or dilatory motive. This is particularly true because the proposed claims are based on facts having to do with the newer plaintiff, Esteve. Being a foreign corporation, Esteve had not been represented by counsel in the United States until being joined in {\*8} this action after the filing of the initial complaint. After

being joined in this action, Esteve had just over three months, pursuant to the March 19, 2003 scheduling order, to obtain any discovery necessary to evaluate potential additional claims and amend the complaint accordingly. Given the foregoing circumstances, it seems that the plaintiffs acted quickly and diligently to investigate Esteve's involvement in the events that gave rise to this action.

Furthermore, permitting Mylan to amend the complaint to include the above-described counts would not significantly prejudice Kremers. The court is not unsympathetic to Kremers' concerns that the addition of the new defendants and claims would require discovery from new third parties and additional discovery from the plaintiff Esteve. However, Mylan sought leave to amend nearly two months before the close of discovery, and the new defendants, Dr. Seth and Dr. Stamm, have already produced documents and been deposed as third parties. In view of Mylan's timely request and considering the discovery that has already been obtained, the court finds that little prejudice would result from re-opening discovery for the limited purpose of obtaining {\*9} additional information on these claims.

#### **B. Mylan's Proposed Amendments Are Not Futile.**

Kremers' remaining arguments against Mylan's proposed amendments, though possibly proper bases for a fully briefed motion to dismiss, are premature reasons for denying Mylan's motion to amend. The court will not determine at this juncture that Mylan lacks standing to bring infringement claims for the '499, '198, and '355 patents. The issue of Mylan's standing to bring an infringement claim for these patents is riveted with factual disputes over the meaning of the Saltrade Agreement. Precedent suggests that Mylan would have standing to bring these claims if the Saltrade Agreement indeed transferred to Esteve legal title in the omeprazole formulation that is the subject of the '499, '198, and '355 patents. See *Speedplay Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000) ("A party that has been granted all substantial rights under the patent is considered the owner regardless of how the parties characterize the transaction that conveyed those rights."); *Filmtec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1573 (Fed. Cir. 1991) (where a contract expressly {\*10} granted rights in any future invention, finding the transfer of title would occur by operation of law). However, to make such a determination the court would have to probe the fact-intensive issue of the scope of the know-how and technology transferred under the Saltrade Agreement. The court will not undertake this kind of inquiry on a motion to amend the complaint.

Because the court at this juncture will not opine ultimately on the issue of Mylan's standing to claim infringement of the '499, '198, and '355 patents, it likewise would be premature for the court to conclude that it lacks subject matter jurisdiction over Mylan's proposed additional state law claims. Where it has original jurisdiction over a federal claim, a district court may exercise supplemental jurisdiction over "all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under **Article III of the United States Constitution.**" 28 U.S.C. § 1367(a). Specifically, supplemental jurisdiction is proper under 28 U.S.C. § 1367 if the state law claims "derive from a common nucleus of operative {\*11} fact" to the federal claims. *United Mine Workers v. Gibbs*, 383 U.S. 715, 725, 16 L. Ed. 2d 218, 86 S. Ct. 1130 (1966). Based on the allegations in the proposed amended complaint, Mylan's state law claims for transfer of ownership, tortious interference, misappropriation of trade secrets and conversion purport to arise from the same or similar set of facts and circumstances that give rise to Mylan's claim of ownership and infringement of the '499, '198, and '355 patents. It therefore appears that the court would have sufficient grounds to exercise supplemental jurisdiction over the additional state law claims if Mylan has properly brought the additional infringement claims. Nevertheless, without expressing a view on Mylan's standing to bring the additional infringement claims, the court cannot determine whether or not to exercise supplemental jurisdiction over the accompanying proposed state law claims.

Kremers' challenge to this court's exercise of personal jurisdiction over Dr. Seth and Dr. Stamm is also not a proper basis for denying Mylan leave to amend the complaint under these circumstances. There is no requirement that a plaintiff allege the facts that support {\*12} a finding of personal jurisdiction in a complaint. See, e.g., *Hansen v. Neumueller GmbH*, 163 F.R.D. 471, 474 (D. Del. 1995) ("Noticeably absent from ... Rule [8] is a requirement of a statement setting forth the grounds upon which the court has personal jurisdiction over the defendant."). In view of this consideration, along with the fact that the parties have not yet developed a record on the possible contacts Dr. Seth and Dr. Stamm may or may not have in the state of Delaware, denying Mylan leave to amend its complaint for lack of personal jurisdiction over these two defendants would be inappropriate.

The court furthermore finds it inappropriate to determine the arbitrability of Mylan's claims on a motion to amend. Generally, the "appropriate procedural mechanism to enforce an arbitration

agreement is a motion to compel, not a motion to dismiss." *West v. Merillat Indus., Inc.*, 92 F. Supp. 2d 558, 561 (W.D. Va. 2000); *see also Strick Corp. v. Cravens Homalloy (Sheffield) Ltd.*, 352 F. Supp. 844, 848 (E.D. Pa. 1972). Moreover, although the Saltrade Agreement does contain an arbitration clause, the actual parties to that contract, { \*13 } Saltrade Ltd. and Laboratorios Esteve, S.A., have not been joined in this action. Given these considerations, it would be premature at this juncture to compel arbitration, particularly where the dispute is among non-parties to the contract.

Likewise, Kremers' argument that Mylan's tort claims are barred by the statute of limitations is also premature. "Unless the complaint, on its face, fails to comply with the applicable limitations period, a motion to dismiss based on the failure to comply with the statute of limitations should be denied." *Tracinda Corp. v. Daimlerchrysler AG* 197 F. Supp. 2d 42, 57 (D. Del. 2002) (citing *In re Equimed, Inc.*, 2000 U.S. Dist. LEXIS 6209, 2000 WL 562909, at \*9 (E.D. Pa. May 9, 2000)). The parties clearly dispute when the proposed claims accrued. Kremers contends that Mylan knew of the claims over six years ago whereas Mylan asserts that it had the opportunity to learn of the defendants' unlawful activities on January 14, 2003, at the earliest. Applying the same standard as for a 12(b)(6) motion, the court will not deny Mylan leave to amend on the grounds that its proposed counts are barred by the statute of limitations.

Finally, construing the { \*14 } allegations of the proposed amendments in the light most favorable to Mylan, the facts underlying Kremers' remaining contentions that the conversion and tortious interference counts fail to state claims upon which relief may be granted, that the Saltrade Agreement does

not transfer a future interest in all omeprazole technology, and that Mylan improperly relies on Delaware law are not sufficiently developed at this time to warrant a finding that the amendments are futile

#### IV. CONCLUSION

In the absence of undue delay, bad faith, or dilatory motive on the part of the movant, repeated failure to cure deficiencies, undue prejudice to the opposing party, or futility of the amendment, the court should exercise its discretion in favor of granting leave to amend. *See Foman*, 371 U.S. at 182; *Cureton*, 252 F.3d at 273. To ensure that cases are decided on the merits rather than on technicalities, the court should use strong liberality in considering whether to grant to leave to amend. *See Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990); *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989); *Heyl & Patterson Int'l, Inc. v. F.D. Rich Housing Virgin Islands*, 663 F.2d 419, 425 (3d Cir. 1981). { \*15 } Having found no dilatory motive or undue prejudice and that the claims would not be futile, the court will exercise its discretion in favor of granting Mylan leave to amend the complaint in the proposed manner

Therefore, IT IS HEREBY ORDERED that:

1. Plaintiff's Motion for Leave to Amend (D.I. 81) is GRANTED.
2. Mylan shall be permitted leave to file the Third Amended Complaint in the form attached as Exhibit A to the Plaintiff's Motion for Leave to Amend.

Dated: November 14, 2003

Gregory M. Sleet

UNITED STATES DISTRICT JUDGE